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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/735,995	12/14/2000	Mark Keating	2323-156	6821

6449 7590 03/09/2002

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WASHINGTON, DC 20005

EXAMINER
SOUAYA, JEHANNE E

ART UNIT	PAPER NUMBER
1634	#3

DATE MAILED: 03/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

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EXAMINER	
SOUAYA, JEHANNE E	
ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 11/27/2001

Remailed 3/9/02

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Office Action Summary

Application No.	Applicant(s)
09/735,995	Keating et al
Examiner	**Art Unit**
Jehanne Souaya	1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Dec 14, 2000* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *11-18, 22-25, 29, and 30* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *11-18, 22-25, 29, and 30* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Currently, claims 11-18, 22-25, and 29-30 are pending in the instant application.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 11-16, drawn to antibodies and a method for diagnosing long QT syndrome using antibody based assays, classified in class 424, subclass 130.1, and class 435, subclass 7.1.

II. Claims 17-18, drawn to a polypeptide comprising a mutation in a HERG polypeptide which causes long QT syndrome and a method to detect long QT syndrome comprising protein based assays, classified in class 530, subclass 350.

III. Claims 22-25 drawn to a method for screening for drugs useful for long QT syndrome, classified in class 435, subclass 4.

IV. Claims 29-30, drawn to a transgenic animal comprising mutant human HERG, classified in class 800, subclass 13.

The inventions are distinct, each from the other because:

2. The inventions of groups I, II, and IV are patentably distinct because they are drawn to different compounds having different structures and functions. The polypeptide of group II is composed of amino acids linked by peptide bonds and can assume complex tertiary structures. While the antibody of group I is also composed of amino acids linked by peptide bonds, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light

chains and 2 heavy chains) associate via disulfide bonds into a Y-shaped symmetric dimer. The transgenic animal of group IV is a composition made up of structurally and functionally complex biological systems. The products of groups I, II, and IV can be used in materially different processes, for example the polypeptide of group II can be used to make a fusion protein with an enzymatic function, the antibody of group I can be used to purify a protein or to identify a particular protein, while the transgenic animal of group IV can be used to express different proteins than HERG. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of groups I, II, and IV are patentably distinct from each other.

3. The inventions of group I, II, and IV are patentably distinct from the invention of group III. The antibody, polypeptide and transgenic animals of the instantly claimed invention are not used in the method of group IV and are unobvious over this method. Consequently, the reagents, reaction conditions and reaction parameters required for each invention are different.

4. Additionally, applicants must further elect no more than 5 mutations to be to be examined, (this is not an election of species) as a search of more than 5 mutations will pose a serious burden on both the examiner and the office. Each mutation codes for a patentably distinct polypeptide, and restriction could be imposed to election of a single mutation (see section 7 below). **However,** the examiner will examine up to 5 mutations.

By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant... to elect that invention to which his claim shall be restricted." 37 CFR 1.142 (a). See also 37 CFR 1.141(a).

Different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such polypeptide sequences are presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 USC 121 and 37 CFR 1.141.

Should applicant traverse on the ground that the sequences are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

6. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, III, or IV, and further because the search for a single mutation from table 7 is not required for a second mutation from table 7, restriction for examination purposes as indicated is proper.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya

Jehanne Souaya
Patent examiner
Art Unit 1655
Nov. 19, 2001